

of Cytotoxic Agents Using *Tetramitus Rostratus*". As the Examiner stated, the claims differ from those of Jaffe in that they recite other flagellates than those taught by Jaffe. This means that the claims are not "identical." As the Examiner acknowledges in the office action, "the term 'same invention,' in this context, means an invention drawn to identical subject matter." The test for the "same invention" is whether one claim could be literally infringed without literally infringing the other; if it could be, claims do not define identically the same invention. (See MPEP § 804), *In re Vogel*, 164 U.S.P.Q. 619, 621 - 622 (CCPA 1970). Because the Examiner acknowledges that the claims are not identical, and because one could literally infringe the claims of the patent without infringing the claims of this application (for example by using a concentrated sample with *T. rostratus* as the organism), and vice versa (for example by using an flagellate other than *T. rostratus*), the rejection for statutory double patenting is plainly in error and should be withdrawn.

The Examiner also rejected Claims 1 - 15 under 35 U.S.C. 103(a) as being unpatentable over Jaffe '508. In support of this rejection, the Examiner again asserts without explanation or support that Jaffe '508 teaches in Examples 5 and 6 a WET test. As stated in the Declaration filed herewith, neither the test of Example 5 nor the test of Example 6 is a WET test. Instead, flagellates are combined with a sample that is augmented with significant amounts of atoxic substance for the purpose of testing the flagellates ability to adapt to a poison. These are not whole effluent samples and there is no teaching of the direct combination of flagellates to a whole effluent sample. If the Examiner disputes this statement, it is requested that he provide (1) evidence in the form of references, or (2) a declaration under 37 CFR § 107(b) establishing his personal expertise and the basis for the opinion. Absent one or the other of these forms of support, Applicant submits that the rejection must be withdrawn.

Applicant further notes that the Examiner apparently places some significance on the teaching in the '508 patent that samples "may be concentrated or, in the case of solids, suspended in a liquid prior to testing." According to the Examiner, the teaching that concentration of the sample is optional suggests that some samples may be able to be used

without concentration, and this in turn is extrapolated by the Examiner to a suggestion for WET testing using *T. rostratus*. Applicant respectfully submits that the conclusions of the Examiner are not supported by the '508 Patent or the relevant facts.

In a WET test, all of the potentially toxic substances from the sample are evaluated in natural combination according to the Environmental Protection Agency guidelines. Procedures such as filtration which remove some toxic substances may not concentrate the remaining toxic substances, but they alter the mixture of toxic substances and thus are not suitable samples for a WET test. Furthermore, it would be appreciated by persons skilled in the arts that some samples might be so rich in toxic substances that concentration of the sample for testing would not be necessary. Thus, because of the difficulty of performing WET tests, and because of the alternative and logical interpretation of the language of the '508 patent, Applicant submits that the Examiner's interpretation of this passage is guided by hindsight and that the Jaffe '508 Patent does not amount to a suggestion of the present invention.

It is further noted that with respect to those claims reciting organisms other than *T. rostratus*, the Examiner has simply asserted that using other flagellates in place of *T. rostratus* (Claim 3 and 6) would have been obvious in view of the teachings of Jaffe '508. The Examiner has not enunciated *why* this is so, however, and thus has plainly failed to present a *prima facie* case that these claims fail to meet the requirements of 35 USC §103. The Examiner has cited no reference in which *T. rostratus* and the other claimed flagellates are described as being equivalent. Furthermore, the Examiner's statement that "it is noted that the present specification teaches specific methods and examples only for *T. rostratus*" is apparently offered as evidence of the obviousness of these claims. To the extent this is the case, it is plainly in violation of the provision of § 103 that patentability cannot be negated by the manner in which the invention is made. The basis for the rejection must be found in the art, and not in the application.

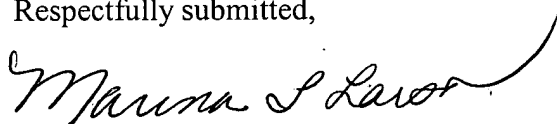
Applicant further notes that the Examiner has not even attempted to address the limitations of many of the dependent claims. Thus, he has not said how the art suggests the steps of claim 7, in which a second test is performed on a filtered sample to provide a comparison of

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the whole effluent sample and a non-whole effluent sample which reflects the presence of toxic particulates, or claim 11 in which a particulate fraction of the whole effluent sample is also tested for comparison.

For the foregoing reasons, Applicant submits that all of the claims of this application are in form for allowance. Favorable reconsideration and allowance of all claims are respectfully urged.

Respectfully submitted,



Marina T. Larson  
Oppedahl & Larson LLP  
P O Box 5270  
Frisco, CO 80443-5270  
970-668-2050  
*marina@patents.com*